

K101551

## 510(k) Summary

SEP 09 2010

Summary Prepared Date: 06/01/2010

### Submission Sponsor:

Delma Medical Instrument (Guangzhou) Co., Ltd.  
17 Xiang Shan Road High and New Technology Industrial Development Zone  
Guangzhou, Guangdong China 510663

### Submission Correspondent:

Mr. Leon Lu  
Director of Regulatory Affairs

MEDevice Services, LLC  
3500 South Dupont Highway  
Dover, Delaware 19901 USA  
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**Trade/Device Name:**  
PACEMAKER High-Speed Handpiece, models PM-MQ and PM-M

**Common or Usual Name:** handpiece, air-powered, dental  
**Device Class:** I

**Classification Name:** handpiece, air-powered, dental

**Regulation Number:** 21 CFR 872.4200

**Product Code:** EFB

**Review Panel:** Dental

### **Predicate Device:**

- K052822, THUNGER TIGER CORP.  
TIGER 100, TIGER 101, TIGER 200, TIGER 201, TIGER 202
- K062812, THUNGER TIGER CORP.  
TIGER 300T, TIGER 300K, TIGER 300W, TIGER 300B, TIGER 300N

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- K062740, JINDELL MEDICAL INSTRUMENTS CO., LTD.  
JINDELL HIGH SPEED AIR TURBINE HANDPIECE, MODELS SW, SP, SU, ETU, MU
  - K093084, ROLENCE ENT INC.  
ROLENCE DENTAL HIGH SPEED HANDPIECE, RHP
  - K063110, SHANGHAI DENTAL INSTRUMENT FACTORY  
CST61 HIGH SPEED TURBINE HANDPIECE
  - K021250, MK-DENT PUSH BUTTON HIGHSPEED HANDPIECE, 4 HOLES, MODELS HS 2012 (STANDARD HEAD) & HS 2014 (SMALL HEAD)

**Device Description:**

The PACEMAKER High-Speed Handpiece is a high speed dental handpiece with a lightly textured finish for enhanced grip. It is a hand-held, channeled instrument that is powered by compressed air that is delivered through a hose to an air channel in the handpiece. This impels the turbine in the head of the handpiece to revolve. Other internal channels deliver air and water to the head for cleaning and cooling. Any common dental bur is held in place in the handpiece head by a push-button.

There are three major parts which are made metal: a standard turbine, the threaded connector at the back end which attaches to the standard air/water hose in the dental unit, and the internal tubes that carry the chip air and water. These three parts are substantially equivalent to those in the predicate device.

Similar to the predicate device, the PACEMAKER High-Speed Handpiece must be cleaned and lubricated with a quality commercial dental handpiece cleaner/lubricant. It is supplied non-sterile, but must be sterilized before use, as with the predicate device. It will be packaged as a single unit or in multiples.

**Intended Use:**

PACEMAKER High-Speed Handpiece, models PM-MQ and PM-M are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.

PACEMAKER High-Speed Handpiece carries the following label:

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**CAUTION:** Federal (US) law restricts the use of this device to licensed professionals.

**Comparison to Predicate Devices:**

The PACEMAKER High-Speed Handpiece is essentially the same as or similar to the predicate device in terms of the intended use, design and construction, performance characteristics. The materials used are well-known biocompatible, so no new issues of biocompatibility are raised with regard to this device.

**Discussion of Non-Clinical Tests Performed:**

The performance of PACEMAKER High-Speed Handpiece following ISO 7785-1:1997 and ISO 9168:1991 were conducted.

Therefore, we conclude that the PACEMAKER High-Speed Handpiece is both safe and effective for its intended use.

**Discussion of Clinical Tests Performed:**

None

**Conclusion:**

The proposed device is as safe and effective as the predicate devices. The proposed device has the same intended uses and indications, similar technological characteristics, and principles of operation as its predicate device. The minor differences between the proposed device and its predicate devices raise no new issues of safety or effectiveness. Thus, the PACEMAKER High-Speed Handpiece, models PM-MQ and PM-M are substantially equivalent to its predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Delma Medical Instrument (Guangzhou) Company, Limited  
C/O Mr. Leon Lu  
MEDevice Services, LLC  
3500 South Dupont Highway  
Dover, Delaware 19901

SEP 09 2010

Re: K101551

Trade/Device Name: PACEMAKER High- Speed Handpiece, models PM-MQ  
and PM-M

Regulation Number: 21 CFR 872.4200

Regulation Name: Dental Handpiece and Accessories

Regulatory Class: I (Non-Exempt)

Product Code: EFB

Dated: August 26, 2010

Received: September 2, 2010

Dear Mr. Lu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

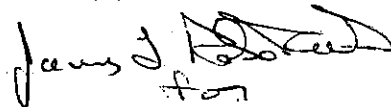
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Anthony D. Watson", is written over a horizontal line.

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

K101551  
SEP 09 2010

### 510(k) Number (if known):

Device Name: PACEMAKER High-Speed Handpiece, models PM-MQ and PM-M

### Indications for Use:

PACEMAKER High-Speed Handpiece, models PM-MQ and PM-M are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.

PACEMAKER High-Speed Handpiece carries the following label:

CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use         
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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